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Flex-Lase 600 Series Ion Laser American Laser Medical November 7, 1996

#### summary of Safety and Effectiveness Information

## Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

## Company Name/Contact;

Company: American Laser Medical

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Regulatory Affairs American Laser Medical 1832 South 3850 West Salt Lake City, UT 84104

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#### Name of Device:

Flex-Lase 600 Series Ion Laser Trade Name:

Common Name: Dermatology Laser

#### Classification:

Powered surgical laser instruments are assigned the unique device classification code 79GEX. The published physical description of this device is found in 21 CFR, & 878.4810 (a) This device classification section specifically describes argon laser systems. The American Laser Medical device may be configured as either an argon laser system or as a krypton laser system, however American Laser Medical maintains that there is no substantial difference between argon and krypton lasers for the purpose of classification. Presently, these lasers are considered Class II medical devices.

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## Description of Device:

The Flex-Lase 600 Series Ion Laser submission covers all of the internal parts, subassemblies and components as well as the completed device. The Flex-Lase Model 640 is a coninuous wave krypton laser system emitting light at the 568 nm (yellow) and 520/530 nm (green) wavelengths. The Flex-Lase Model 620 is a continuous wave argon laser system emitting light at the 488 nm (blue) and the 514 nm (green) wavelengths.

Treatment beam output for the Flex-Lase Model 640 (krypton) is 1.0 Watt (yellow) and 3.0 Watts (yellow-green simultaneous). The power output for the Flex-Lase Model 620 (argon) is 5.5 watts blue-green or 2.0 watts green. The aiming beam is provided by an adjustable intensity incoherent white light source. Exposure times for the Flex-Lase 600 Series Ion Laser (in seconds) are 0.02, 0.05, 0.1, 0.25, 0.5, 1.0, and continuous.

Laser activation occurs by footswitch. Overall weight of the system is 112 lbs. (51 kg). The Flex-Lase 600 Series Ion Laser has a footprint of 16 X 24 inches (38 X 60 cm) and is 36 inches (90 cm) high.

The electrical power requirement is 208 VAC 40 amp single phase. Cooling is provided by external filtered flow-through tap water at a minimum rate of 2.5 gallons (9.5 liters) per minute.

Accessories available for use with the Flex-lase 600 Ion Laser include a focusing handpiece with interchangeable guide tips and/or the Hexascan Mark II. The Flex-laser 600 series is not a computer controlled device.

#### Intended Use:

The Flax-lass 600 Series Ion Laser is intended for use in the treatment of selected vascular and pigmented lesions of the skin. Laser light of a selected wavelength is used to photocoagulate tissue based on the absorption characteristic of the targeted chromophore within the tissue.

#### Indications for Use:

The Flex-Lase 600 Ion Laser is intended for use in the treatment of selected pigmented and vascularized lesions of the skin. Representative indications for use are:

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## Flex-Lase Model 640 Laser System For vascular lesions: (Yellow - 568 nm)

- 1. Capillary Hemangioma (port wine hemangioma)
- 2. Strawberry hemangioma
- 3. Telangectasia
- 4. Rosacea

## For pigmented lesions: (Yellow/Green - 568 nm and 520-530 nm).

- 1. Freckles
- 2. Age Spots
- 3. Cafe-au-lait
- 4. Lentigo

# Flex-Lase Model 620 Laser System For Vascular Lesions: (Blue/Green - 488 nm and 514.5 nm)

- 1. Capillary Hemangioma (port wine hemangioma)
- 2. Strawberry Hemangioma
- 3. Telangectasia
- 4. Rosagea

# For pigmented lesions: (Green - 514.5 nm)

- 1. Freckles
- 2. Age Spots
- 3. Cafe-Au-Lait
- 4. Lentigo

## Comparison of Device Characteristics:

#### For vascular lesions:

The Flex-Lase 600 Ion Laser System is substantially equivalent to the MGM Spectrum K1, the Hetalaser Vasculase and the Coherent Artisan already in commercial distribution. The materials, design, intended use, method of manufacture, warnings, cautions, precautions and treatment parameters are substantially the same.

# For pigmented lesions:

The Flex-Lage 600 Series Ion Laser system is substantially equivalent to the HGM Spectrum K1, the Metalaser Vasculase and the Coherent Artisan already in commercial distribution. The

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> materials, design, intended use, method of manufacture, warnings, cautions and precautions are substantially the same.

> Feature comparison tables which follow illustrate the equivalence of features of the Flex-Lase 600 and equivalent available systems. See also appendix II for marketing materials on substantially equivalent devices.

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# Laser Equivalency Table Vascular Lesions

XXXXX 7-10	PLEX-LASE MODEL 620	FLEX-LASE MODEL 640	HGM K1	METALASER VASCULASE	COHBRENT ARTISAN
Туре	Con- tinuous. wave argon	Continuous wave krypton	Continuous Wave krypton	Copper Vapor Laser	Continuous wave Argon/Dye
Wavelength (nano- meters)	514 , or 488/514	568, or 568/520- 530	568, 520/530	511, 578	514 only, or 488/514, or 577-630 selectable
Exposure Time (sec.)	0.02, 0.05, 0.1, 0.25, 0.5, 1.0, and cont.	Same	0.05, 0.1, 0.2, 0.5, 1.0, 2.0, 5.0, and continuous	0.075, 0.1, 0.2, 0.3, and continuous	0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1.0, 2.0, 5.0, cont.
Output Mode	Multimode	Multimode	Multimode	Multimode	Multimode
Beam Delivery	Handpiece via fiber optic	Handpiece via fiber optic	Handpiece via fiber optic	Handpiece via fiber optic	Handpiece via fiber optic
Stability of Output Energy	+/- 10%	+/- 10%	+/- 10%	+/- 20%	+/- 5%
Spot Size (mm)	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.1, 0.2,	0.1, 0.2,	0.1, 0.25, 0.5, 1.0, fixed, variable 0.2-2.5
Energy density	2~30 J/cm <sup>2</sup>	2-30 J/cm <sup>2</sup>	2-30 J/cm <sup>2</sup>	4-15 J/cm <sup>2</sup>	2-30 J/cm <sup>2</sup>
Aiming beam	Adjust- able in- coherent white light source	Adjustable incoherent white light source	HeNe (633nm) adjustable to 5 mW	HeNe (633 nm)	HeNe (633 nm)

Range A	PLEX-LASE MODEL 620	FLEX-LASE MODEL 640	EGH K1	METALASER VASCULASE	Coherent Artisan
Cooling	Filtered flow- through tap water 2.5 gal/min	Filtered flow- through tap water 2.5 gal/min	Internal liquid cooled	Air- ccoled, 40F-80F ambient air temp.	Filtered flow- through tap water 2.5 gal/min
Blectrical Require- ments	208-240 VAC 40 amp single phase 50/60 Hz	208-240 VAC 40 amp single phase 50/60 Hz	208-240 VAC 40 amp 50/60 Hz single phase	208 VAC +/- 10%, 20 amp 60Hz single phase	208 VAC 50 amp 50/60 Hz 3 phase
Indications for Vascular lesions	Capillary (port wine) heman- gioma, Straw- berry heman- gioma, Telangec- tasia, Rosacea	Capillary or port wine hemangioma Strawberry hemangioma Telangec- tasia Rosacea	Vascular Lesions (same)	Vascular Lesions (same)	Vascular Lesions (same)
K Number			K913428, K913569	K903883	na

# Laser Equivalency Table Figmented Lesions

<b>District</b>	FLEI-LASE MODEL 620	FLEX-LASE MODEL 640	EGM K1	METALASER VASCULASE	COHERENT ARTISAN
Type	Con- tinuous wave argon	Continuous wave krypton	Continuous Wave krypton	Copper Vapor Laser	Continuous wave Argon/Dye
Wavelength (nano- meters)	514, or 488/514	568, or 568/520- 530	568, 520/530	511, 578	514 only, or 488/514, or 577-630 selectable
Exposure Time (sec.)	0.02, 0.05, 0.1, 0.25, 0.5, 1.0, and cont.	Same	0.05, 0.1, 0.2, 0.5, 1.0, 2.0, 5.0, and continuous	0.075, 0.1, 0.2, 0.3, and continuous	0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1.0, 2.0, 5.0, cont.
Output Mode	Multimode	Multimode	Multimode	Multimode	Multimode
Beam Delivery	Handpiece via fiber optic	Handpiece via fiber optic	Handpiece via fiber optic	Handpiece via fiber optic	Handpiece via fiber optic
Stability of Output Energy	+/- 10%	+/-10%	+/-10%	+/-20%	+/- 5%
Spot Size (milli- meters)	0.25, 0.5, 1.0	0.25, 0.5, 1.0	0.1, 0.2, 1.0 mm	0.1, 0.2, 1.0 mm	0.1, 0.25, 0.5, 1.0, fixed, variable 0.2-2.5 mm
Energy density	2-30 J/cm <sup>2</sup>	2-30 J/cm <sup>2</sup>	2-30 J/cm <sup>2</sup>	4-15 J/cm <sup>2</sup>	2-30 J/cm <sup>2</sup>
Aiming beam	Adjust- able in- coherent white light source	Adjustable incoherent white light source	HeNe (633nm) adjustable to 5 mW	HeNe (633 nm)	HeNe (633 nm)

	PLBI-LASE MODEL 620	FLEX-LASE WODEL 640	BOM K1	METALASER VASCULASE	COHERENT ARTISAN
Cooling	Filtered flow- through tap water 2.5 gal/min	Filtered flow- through tap water 2.5 gal/min	Internal liquid cooled	Air- cooled, 40F-80F ambient air temp.	Filtered flow- through tap water 2.5 gal/min
Electrical Require- ments	208-240 VAC 40 amp single phase 50/60 Hz	208-240 VAC 40 amp single phase 50/60 Hz	208-240 VAC 40 amp 50/60 Hz single phase	208 VAC +/+ 10%, 20 amp 60Hz single phase	208 VAC 50 amp 50/60 Hz 3 phase
Indications for Pigmented lesions	Frackles, Age spots, cafe-au- lait, lentigo	Freckles, Age spots, cafe-au- lait lentigo	Pigmented Lesions (same)	Pigmented Lesions (same)	Pigmented Lesions (same)
K Number			K913428, K913569	K903883	na